Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 6/20/2017 4:59:57 PM
To: Pierce, Alison [Pierce.Alison@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]
CC: Canavan, Sheila [Canavan.Sheila@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]
Subject: RE: Due ASAP FW: For final review -- GenX statement

Alison, I just send the version from Jeff to all the coms directors and OPA.

Let me know if there were inaccuracies to that what Jeff sent. If not, I'll keep it the same as this has gone through multiple reviews by all the offices including R4.

Thanks very much.

Linda

From: Pierce, Alison
Sent: Tuesday, June 20, 2017 12:54 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

I've taken a crack at incorporating what OPPT submitted up earlier this a.m. into the e-mail trail below (red-line/strike out). We had responded to a set of press questions that are clearly linked, but it's an awkward 1-for-1 substitution. Those suggested responses are here for reference:

> 1.What does EPA know about the toxicity and persistence of GenX?
> When EPA reviewed the Pre-manufacture Notice for GenX, concerns for persistence and toxicity were identified based on studies on GenX and for the analog PFOA (also known as C8). Based on these concerns, EPA issued a consent order, which required testing, among other things, including limitations on releases to water and worker protection.
>
> 2. Has Chemours submitted any testing data on GenX to the EPA?
> As part of a Consent Order, EPA required Chemours to conduct and submit to EPA the following toxicity tests: (1) Repeated-dose Metabolism and Pharmacokinetics study in rats; (2) Repeated-dose Metabolism and Pharmacokinetics study in mice; (3) 90-day Toxicity Study; (4) Modified 1-Generation Reproduction study in rats; (5) Combined Oral Gavage Chronic Toxicity/Oncogenicity test in rats; (6) Fish Early Life Stage Toxicity Test; and Daphnid Chronic Toxicity Test. Chemours has submitted that data and EPA is updating its risk assessment.

From: Beck, Nancy
Sent: Tuesday, June 20, 2017 12:06 PM
To: Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

I'm late to the party. So whats the current version? Does below capture Jeffs suggestions?

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP
P: 202-564-1273
Ex. 5 Deliberative Process (DP)

From: Cleland-Hamnett, Wendy
Sent: Tuesday, June 20, 2017 11:51 AM
To: Henry, Tala <Henry.Tala@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

I agree that it should be "risk" not "toxicity" assessment.

Wendy Cleland-Hamnett
Acting Assistant Administrator
Principal Deputy Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
202-564-2910
cleland-hamnett.wendy@epa.gov

From: Henry, Tala
Sent: Tuesday, June 20, 2017 11:40 AM
To: Morris, Jeff <Morris.Jeff@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

We did have data (28-day) for GenX which was used in the PMN Risk Assessment, along with PFOA as an analog

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959
E: henry.tala@epa.gov

From: Morris, Jeff
Sent: Tuesday, June 20, 2017 10:45 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

I had made comments this morning, which may not have made it to this version. I imagine it would have been the PMN assessment, and it would have been a risk assessment. We would have done the assessment on the best analog, since data were only subsequently generated and submitted per the consent order.

From: Beck, Nancy
Sent: Tuesday, June 20, 2017 10:03 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

So the highlighted language below presumes we have a toxicity assessment. Is this referring to the PMN review? Is this really a toxicity assessment? Also this implies that in this review, analysis was based on what we know about PFOA—however aren't they structurally different? Would PFOA have been a good analogue?

One additional edit on the last sentence as well.
Thanks.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
N Ex. 5 Deliberative Process (DP)
beck.nancy@epa.gov

From: Strauss, Linda
Sent: Tuesday, June 20, 2017 9:59 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>
Subject: Due ASAP FW: For final review -- GenX statement

Nancy and Wendy, take a look at this version.

From: Grantham, Nancy
Sent: Tuesday, June 20, 2017 9:49 AM
To: Marraccini, Davina <Marraccini.Davina@epa.gov>; Harris-Young, Dawn <Harris-Young.Dawn@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Maguire, Megan <Maguire.Megan@epa.gov>; Senn, John <Senn.John@epa.gov>
Cc: Jones, Enesta <Jones.Enesta@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: For final review -- GenX statement

All – per our call just a few minutes ago, here is the final holding statement. Please make sure that your principals review asap – including Nancy Beck, Patrick Trailor, Sarah Greenwalt, and Richard Yamada.

Thanks all

ng

EPA is committed to protecting public health and supporting states and public water systems as the appropriate steps to address the presence of GenX in drinking water are determined.

EPA is initiating an investigation into Chemours's compliance with a 2009 order issued under the Toxic Substances Control Act (TSCA) for the production of GenX. This investigation will allow EPA to determine whether Chemours is in compliance with requirements of the order to control releases to the environment at the Fayetteville, N.C., facility. As part of that consent order, EPA required Chemours to conduct and submit to EPA additional toxicity tests. Chemours has submitted that data and EPA is updating its risk assessment. ~~EPA is also reviewing the additional toxicity data submitted by the company, as required under the consent order, and updating the toxicity assessment using the more robust toxicity database specific to GenX.~~ At the request of the North Carolina Department of Environmental Quality (NCDEQ), EPA has agreed to perform independent laboratory analysis for GenX in some of the water samples being collected by NCDEQ at 13 locations in the Cape Fear River over the next three weeks.

Background

- Typically, EPA investigates potential TSCA noncompliance through a review of production and environmental controls records required by any rule or order and, as needed, an on-site inspection. EPA may also use information requests to inform our investigation.
- When EPA reviewed the Pre-manufacture notice for GenX, concerns for persistence and toxicity were ~~issued the consent order, the toxicity assessment for GenX was~~ based on the available toxicity data for GenX and for the analog PFOA (also known as C8). Based on these concerns, EPA issued a ~~The~~ consent order, which required ~~the company to conduct additional toxicity~~ testing, among other things, including limitations on releases to water and worker protection. ~~on GenX.~~
- Chemours agreed to bear all costs for the water collection and testing. The samples are being sent to a private laboratory in Colorado, and the EPA Office of Research and Development laboratory in Research Triangle Park, NC for independent verification.

NCDEQ believes the completed results will be back from the laboratory in Colorado within four weeks from when the samples are received. EPA is working to determine a timeline for its analysis.

Under the Safe Drinking Water Act, EPA undertakes extensive evaluations of contaminants and uses the best available peer reviewed science to identify and regulate contaminants that present meaningful opportunities for health risk reduction.

~~While EPA has not established a drinking water regulation, health advisory or health based benchmark for GenX in drinking water,~~ The agency is working closely with the states and public water systems to determine the appropriate next steps to ensure public health protection.

Nancy Grantham
Office of Public Affairs
US Environmental Protection Agency
202-564-6879 (desk)
Ex. 5 Deliberative Process (DP)
~~202-809-7666 (mobile)~~